

**ASX/ Media Release**  
**21 December 2017**

## **Progress Update on Global Pancreatic Cancer Clinical Study Programme**

**Sydney, Australia, 21 December 2017:** OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**) a medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to provide an update on the progress of its Global Pancreatic Cancer Clinical Study Programme.

### **Highlights**

- **28 subjects now enrolled into Global Pancreatic Cancer clinical study**
- **18 subjects implanted with the OncoSil™ device**
- **20<sup>th</sup> subject implant scheduled for early January 2018**
- **Excellent local disease control – Disease Control Rate (DCR) 100% @Week 8, 90% @Week 16**
- **No Serious Adverse Events attributed to device or implantation procedure**

OncoSil Chief Executive Officer, Daniel Kenny commented:

*“We are pleased to report that OncoSil Medical is nearing the 20<sup>th</sup> subject implantation, scheduled for early January 2018. More importantly we are very encouraged by the positive early data from the first group of patients completing Week 8 and Week 16 follow-up assessments.”*

### **Study Update**

OncoSil continues to progress recruitment of its study, with **28** subjects now enrolled into the current study group, and with 18 implants completed to date. The 20<sup>th</sup> implant of the OncoSil™ device is scheduled for early January 2018. The promising early safety, efficacy and implant delivery data is consistent with the data obtained from previously completed studies with the OncoSil™ device.

### **Clinical performance**

18 subjects have been implanted with the OncoSil™ device.

- 15 subjects have reached Week 8 radiological evaluation,
- 10 subjects have reached Week 16 radiological evaluation,
- 4 subjects have reached Week 24 radiological evaluation.
- Disease Control rate at Week 8 is 100%
- Disease Control rate at Week 16 is 90%
- Early and substantial tumour volumetric reduction - up to 73% observed at Week 8 (4 weeks post implant) and up to 72% at Week 16 (12 weeks post implant)

## Safety

Reassuring safety profile as confirmed by two Independent Safety Review Committee meetings (September and November 2017)

- No Serious Adverse Events (SAEs) attributed to device or implantation procedure
- SAEs related to chemotherapy or complications arising from cancer progression
- No evidence of radiation toxicities
- No other safety concerns identified to date

## Implantation Procedure

OncoSil™ device delivery via Ultrasound guided endoscopy (EUS) is considered straightforward and uncomplicated.

As previously announced to the market, the Company will continue to recruit subjects beyond the initial 20-subject target to gather additional valuable clinical experience and to account for subject loss due to factors such as withdrawal on clinical grounds prior to implantation or protocol ineligibility.

- ENDS -

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## About OncoSil

OncoSil™ is a clinical-stage medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil™ is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with the OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical trials with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil™ in the European Union (EU) is under review with commercial launch planned for 2H2016, subject to approval.

The U.S Food and Drug Administration granted an Investigational Device Exemption (IDE) in July 2016 with approval to conduct a clinical study of the OncoSil™ device. The aim of the study will be to collect safety and effectiveness data required to support a Premarket Approval (PMA) application.

Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil™ in pancreatic cancer exceeds \$1b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6<sup>th</sup> most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.

## Forward Looking Statements

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.